

In the Claims

Please add new claims 24-31 as follows:

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1. (Previously Amended) A valve for a tubular peel-away sheath having a lumen therethrough comprising:

a valve body having a lumen therethrough;

means for preferentially breaking said valve body along a predetermined location in response to applied force, such that said valve body lumen splits open upon breaking;

means for coupling said valve body to said peel-away sheath for coupling said peel-away sheath lumen to said valve body lumen;

means for receiving a compressible valve sleeve;

a compressible valve sleeve having a proximal end, a distal end, and a lumen adapted to receive a distal portion of a medical device; and

means for compressing said valve sleeve for restricting any fluid flow from said peel-away sheath lumen through said valve and valve sleeve lumen, said proximal end of said compressible valve sleeve extending proximal of said means for compressing said valve sleeve.

2. (Original) A valve as recited in claim 1, wherein said valve sleeve includes a free end extending past said means for compressing, and further comprising means for receiving a catheter tip within said valve sleeve lumen free end while said means for compressing is compressing said valve sleeve, such that said valve sleeve lumen is substantially occluded by said inserted catheter tip while said catheter tip is inserted.

3. (Previously Amended) A breakaway valve for a tubular peel-away sheath, said sheath having an external surface, a lumen, and a proximal end comprising:

① means for reversibly restricting fluid flow from said sheath lumen coupled to said sheath proximal end, wherein said means for reversibly restricting fluid flow includes a compressible valve sleeve and means for compressing said valve sleeve, said valve sleeve having a proximal end and a distal end and a lumen therethrough, the proximal end of said valve sleeve extending proximal of said means for reversibly restricting fluid flow and adapted to admit a catheter distal end into said valve sleeve lumen; and

means for breaking apart said fluid flow restricting means responsive to applied force.

4. (Original) A breakaway valve as recited in claim 3, wherein said means for reversibly restricting flow has an open position for allowing flow therethrough and a closed position for substantially restricting flow, wherein said means for admitting said catheter distal end includes means for admitting said catheter distal end while said means for restricting flow is in said closed position.

5. (Original) A breakaway valve as recited in claim 4, wherein said means for restricting flow includes a flexible, constrictable tube having a lumen therethrough.

6. (Original) A breakaway valve as recited in claim 5, wherein said means for restricting flow includes means for pinching said flexible tube for constricting said flexible tube lumen.

7. (Original) A breakaway valve as recited in claim 6, wherein said means for pinching has at least two portions movable with respect to each other, said two portions having means for accepting and pinching said flexible tube therebetween, said two portions together having an open position and a closed position.

8. (Original) A breakaway valve as recited in claim 7, wherein said movable pinching member portions are hingedly coupled together with at least one hinge.

9. (Original) A breakaway valve as recited in claim 8, wherein said sheath has a longitudinal axis and said at least one hinge has an axis substantially parallel with said sheath longitudinal axis and said hinge enables movement of said pinching member portions about said hinge longitudinal axis for pinching said flexible tube in said closed position.

10. (Withdrawn)

11. (Original) A breakaway valve as recited in claim 8, wherein, when in said closed position, said pinching members include means for leaving sufficient space in said flexible tube lumen for passage of a guide wire.

12. (Previously Amended) An introducer sheath assembly for introducing a catheter distally into a human body comprising:

a tubular, distal introducer sheath having a proximal region and a lumen therethrough, said sheath having at least one longitudinal strip for preferentially tearing said sheath along said

strip;

a tubular, compressible, proximal valve sleeve having a proximal region, a distal region, and a lumen therethrough; and

11 a valve body having a lumen therethrough and being sealingly coupled to said introducer sheath proximal region, said valve having at least one weakened region for preferentially splitting said valve into at least two pieces responsive to an applied breaking force, said valve body having a seat for mating to said proximal valve sleeve distal region, said valve body including a pinch member for pinching said flexible valve sleeve and having a closed position for constricting fluid flow through said valve sleeve and an open position for admitting a catheter inserted through said valve sleeve; wherein said proximal region of said proximal valve sleeve extends proximal of said pinch member and is adapted to receive a medical device.

13. (Original) An introducer sheath assembly as recited in claim 12, wherein said flexible valve sleeve includes a free portion proximal of said pinch member for admitting said catheter into said sleeve free portion while said pinch member is in said closed position.

14. (Original) An introducer sheath assembly as recited in claim 12, wherein said valve body pinch member includes a recess therein for allowing passage of a guide wire through said pinch member while said pinch member is in said closed position.

15. (Previously Amended) A breakaway valve body for restricting flow from a peel-away introducer sheath having a proximal region and a lumen therethrough comprising:

a breakaway distal portion having a lumen therethrough for receiving said introducer

sheath proximal region; and

1) a proximal portion including two opposed valve body members, at least one of which is movable relative to the other and having concave surfaces therebetween for receiving a flexible valve sleeve therebetween, said valve body opposed members having an open position and a closed position, wherein said valve body members move apart relative to each other to reach said open position and said valve body opposed members move together relative to each other to reach said closed position, wherein said flexible sleeve has a lumen therethrough adapted to receive a medical device, said flexible sleeve having a proximal end, and a distal end, said proximal end extending proximal of said body members, said sleeve being compressible, and said sleeve and sleeve lumen are constricted between said body members in said closed position, such that fluid flow through said sleeve is substantially restricted in said closed position.

16. (Withdrawn)

17. (Withdrawn)

18. (Withdrawn)

19. (Withdrawn)

20. (Withdrawn)

21. (Original) A breakaway valve body as recited in claim 15, wherein said valve

body members are pivotally mounted to each other along at least one hinge oriented substantially parallel to said valve body lumen longitudinal axis.

22. (Withdrawn)

23. (Withdrawn)

24. (Newly presented) A valve mechanism for attachment to an introducer sheath, the valve mechanism comprising:

a sheath receiver at a distal end of the valve mechanism, the sheath receiver adapted to receive the proximal end of an introducer sheath; and

a pinch member having an open configuration and a closed configuration, the pinch member sized to receive a compressible valve sleeve;

wherein the sheath receiver and the pinch member are placed such that:

when a compressible valve sleeve having a lumen is received by the pinch member and an introducer sheath having a lumen is received by the sheath receiver, fluid communication is created from the introducer sheath lumen into the compressible valve sleeve lumen.

25. (Newly presented) A valve mechanism as in claim 24 wherein, when a compressible valve sleeve is received by the pinch member and the pinch member is in the closed configuration, fluid flow through the compressible valve sleeve is substantially prevented.

26. (Newly presented) A valve mechanism as in claim 24 wherein, when a compressible valve sleeve with a guidewire inserted therethrough is received by the pinch member and the pinch member is in the closed configuration, fluid flow through the compressible valve sleeve is substantially prevented.

27. (Newly presented) A valve mechanism as in claim 24 further comprising a valve sleeve seat for receiving a distal end of a compressible valve sleeve, wherein the valve sleeve seat is located between the pinch member and the sheath receiver.

28. (Newly presented) A valve system for attachment to an introducer sheath, the valve system comprising:

a compressible valve sleeve having a proximal end, a distal end, and a lumen therethrough; and

a valve mechanism including a sheath receiver adapted to receive the proximal end of an introducer sheath and a pinch member having an open configuration and a closed configuration and sized to receive the compressible valve sleeve;

wherein the sheath receiver and the pinch member are placed such that:

when the compressible valve sleeve is received by the pinch member and an introducer sheath having a lumen is received by the sheath receiver, fluid communication is created from the introducer sheath lumen into the compressible valve sleeve lumen.

29. (Newly presented) A valve system as in claim 28 wherein, when the compressible valve sleeve is received by the pinch member and the pinch member is in the closed configuration, fluid flow through the compressible valve sleeve is substantially prevented.

30. (Newly presented) A valve system as in claim 28 wherein, when the compressible valve sleeve with a guidewire inserted therethrough is received by the pinch member and the pinch member is in the closed configuration, fluid flow through the compressible valve sleeve is substantially prevented.

31. (Newly presented) A valve system as in claim 28 wherein the valve mechanism further includes a valve sleeve seat for receiving the distal end of the compressible valve sleeve, the valve mechanism having a proximal end and a distal end, with the pinch member being proximal of the valve sleeve seat and the valve sleeve seat being proximal of the sheath receiver.

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